

Application No. 10/658,116  
Amendment dated March 23, 2009

Docket No.: VALT-004-102

### REMARKS

#### Rejection of Claims 29-33 and 35 Under 35 U.S.C. §102(b)

Claims 29-33 and 35 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Lindmayer *et al.* (U.S. Patent 4,623,332). Applicants respectfully traverse this rejection, as Lindmayer *et al.* does not teach, *inter alia*, a movable piston having an end and at least one relief hole. The Examiner alleges that the bifurcated piston 51 of Lindmayer *et al.* meets the limitation of a movable piston having at least one relief hole. However, careful review demonstrates that piston 51 may have a cavity defined by the bifurcations but does not comprise a hole. Indeed, there is no need for piston 51 to comprise a hole, as it does not contain an agent (e.g., gas or liquid) which requires egress from within the piston; Applicants note that the device of Lindmayer *et al.* is not gas-actuated but rather spring-actuated. Because Lindmayer *et al.* does not teach or suggest all elements of claims 29-33 and 35, Lindmayer *et al.* does not anticipate these claims. Reconsideration and withdrawal of the rejection are respectfully requested.

#### Rejection of Claims 1 and 27-28 Under 35 U.S.C. §102(e)

Claims 1 and 27-28 are rejected under 35 U.S.C. §102(e) as allegedly anticipated by Jacobsen *et al.* (U.S. Patent 6,165,155). Applicants respectfully traverse this rejection and note that Claim 1 has been amended to recite a needleless injection device. Claims 27 and 28 incorporate this limitation as dependent claims of claim 1.

The Examiner points to Figures 8A-8D and the corresponding portions of the specification as disclosing the elements of claims 1, 27 and 28. The identified embodiments of Jacobsen *et al.*, however, disclose hypodermic needle drug delivery devices. There is no teaching or suggestion of these elements, which the Examiner alleges correspond to the recitations of the subject claims, in connection with needleless injection devices. Moreover, Jacobsen *et al.* teach at col. 11, lines 52-55, that the "internal structure is necessarily more complicated in design because a needle must not only be injected into the patient, but the drug delivered and the needle subsequently withdrawn." Thus, it is clear that the reference actually teaches away from including these elements in a needleless device because they would

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unnecessarily complicate the design of such a device. Accordingly, Jacobsen *et al.* does not teach or suggest all elements of claims 1 and 27-28; thus, Jacobsen *et al.* does not anticipate these claims. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 1 and 27-35 Under Judicially Created Doctrine of Obviousness-Type  
Double Patenting

Claims 1 and 27-35 are rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1-23 of U.S. Patent No. 6,616,627. Applicants do not address the merits of this rejection at this time, as the relevance of the rejection to the claims of the subject application which may ultimately be found allowable has yet to be determined. Applicants will address the merits of the rejection and/or file a Terminal Disclaimer as appropriate at that time. Should the Examiner find that this Amendment overcomes all outstanding rejections and that the claims are otherwise in condition for allowance, Applicants invite the Examiner to contact the undersigned by telephone to expedite addressing the double patenting rejection.

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### CONCLUSION

In view of the above remarks and amendments, Applicants respectfully submit that the application is in condition for allowance. If the Examiner believes that a telephone call would be useful in expediting the allowance of the application, the Examiner is invited to contact the undersigned.

Applicant believes that no fee is due for the response other than the fees provided for on the accompanying transmittal. However, if an additional fee is due, please charge Deposit Account No. 50-3655, from which the undersigned is authorized to draw, under order number VALT-004-102.

Dated: March 23, 2009

Respectfully submitted,

By Lisa M. Treannie

Lisa M. Treannie, Esq.  
Registration No.: 41,368  
Morse, Barnes-Brown & Pendleton, P.C.  
Reservoir Place  
1601 Trapelo Road, Suite 205  
Waltham, MA 02451  
781-622-5930  
Attorneys for Applicant